

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

CITY OF CHARLESTON, WEST VIRGINIA,
CITY OF HUNTINGTON, WEST VIRGINIA,
CITY OF KENOVA, WEST VIRGINIA, and
TOWN OF CEREDO, WEST VIRGINIA,
municipal corporations, and other municipal
corporations similarly situated,

Plaintiffs,

v.

Civil Action No. 2:17-cv-04267

THE JOINT COMMISSION f/k/a
THE JOINT COMMISSION ON ACCREDITATION OF HEALTH
CARE ORGANIZATIONS, a not-for-
profit organization, and its wholly-owned
affiliate, JOINT COMMISSION
RESOURCES, INC. d/b/a JOINT
COMMISSION INTERNATIONAL, a
not-for-profit organization,

Defendants.

MEMORANDUM OPINION AND ORDER

Pending are (1) defendant The Joint Commission's
motion to dismiss plaintiffs' complaint, or in the alternative,
strike class action allegations, filed January 29, 2018;
(2) defendant Joint Commission Resources, Inc.'s motion to
dismiss, filed January 29, 2018; and (3) defendants' motion for
scheduling order for submission of amicus curiae briefs, filed
March 14, 2018.

The three-count complaint consists of Count I negligence, gross negligence, reckless and willful conduct; Count II unjust enrichment; and Count III equitable relief.

I. The Parties

Plaintiffs in this case are the City of Charleston, City of Huntington, City of Kenova, and Town of Ceredo, West Virginia, on behalf of themselves and other similarly situated municipalities across the nation ("the Municipalities"). Defendant The Joint Commission f/k/a The Joint Commission on Accreditation of Health Care Organizations ("TJC")¹ is a not-for-profit organization that accredits and certifies approximately 21,000 public and private health care organizations ("HCOs") and programs in the United States. In addition to accrediting hospitals, as was its purpose when founded in 1951, TJC provides accreditation for other types of HCOs as well including home care organizations, long term care, behavioral health care, ambulatory care, and laboratory

¹ According to its motion to dismiss, The Joint Commission on Accreditation of Health Care Organizations does business as The Joint Commission, and plaintiffs improperly identified it as "The Joint Commission f/k/a The Joint Commission on Accreditation of Health Care Organizations" in the complaint. See TJC's Mem. Supp. Mot. Dismiss & Mot. Strike 1, ECF No. 20.

services.² The HCOs include several hospitals where plaintiffs' residents receive health care.³ Compl. ¶ 14.

TJC was founded in 1951 by the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association with the American College of Surgeons.⁴ With offices in Illinois and Washington, D.C., TJC is the "oldest and largest health care standards setting and performance improvement organization" in the United States. TJC's Mem. Supp. Mot. Dismiss & Mot. Strike 2, ECF No. 20 ("ECF No. 20"). Today, TJC describes its mission as "continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and

² See Motion for Leave to File Brief Amicus Curiae; and Brief Amicus Curiae of The Joint Commission in Support of Petitioners, Christie v. Adkins, No. 07-538 (U.S. Nov. 21, 2007), 2007 WL 4178499.

³ The HCOs in the area where plaintiffs' residents receive health care include Charleston Area Medical Center ("CAMC") General Hospital, CAMC Memorial Hospital, CAMC Women's and Children's Hospital, Highland Hospital, St. Francis Hospital, Thomas Memorial Hospital, St. Mary's Medical Center, Cabell Huntington Hospital, Mildred Mitchell- Bateman Hospital, and River Park Hospital. Compl. ¶ 14.

⁴ See Katharine Van Tassel, Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines, 36 Seton Hall L. Rev. 1179, 1188 (2006). The American College of Surgeons, or ACS, was responsible for implementing minimum safety and performance standards based on its Hospital Standardization Program. In 1952, ACS transferred the Hospital Standardization Program to TJC. Id.

effective care of the highest quality and value." Compl. ¶ 14; see also Niven v. Siqueira, 487 N.E.2d 937, 941 (Ill. 1985) (summarizing TJC's basis purpose, as described in its Accreditation Manual for Hospitals, "to establish standards for the operation of health care facilities, to conduct survey and accreditation programs that encourage and assist health care facilities in the task of promoting efficient, high quality patient care, and to recognize compliance with their standards by issuance of certificates of accreditation").

TJC is governed by a 29-member Board of Commissioners, including physicians, administrators, nurses, quality experts, and educators as well as representatives from each of the Joint Commission's five Corporate Members: American Hospital Association, American Medical Association, American College of Physicians, American College of Surgeons, and American Dental Association.⁵ Part of TJC's work involves promulgating standards based on extensive literature review, input from national experts and other stakeholders in the industry, and after conducting public field reviews. ECF No. 20 at 2. TJC also conducts on-site accreditation surveys of HCOs, for which its

⁵ See Motion for Leave to File Brief Amicus Curiae, Christie, 2007 WL 4178499, at *1; Timothy S. Jost, The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest, 24 B.C. L. Rev. 835, 840 (1983).

standards serve as a guide. In addition to its accreditation services, TJC offers certification options for HCOs that meet standards in disease specific categories of care, such as stroke and heart failure. Id.⁶ According to the complaint, TJC "has assets of roughly \$190 million and receives over \$150 million in revenue each year, largely from its certification programs." Compl. ¶ 14. Moreover, because TJC accredits "99% of health care organizations in the United States," most HCOs deem losing TJC accreditation "as disastrous to their continued operation." Id. ¶ 16.

Both the federal and state governments rely on TJC's accreditation process. HCOs that receive accreditation by TJC, as an approved national accrediting organization, are statutorily "deemed" in compliance with federal requirements and eligible to participate in Medicare and Medicaid programs without a separate government inspection. 42 U.S.C. § 1395bb(a); 42 C.F.R. §§ 488.5, 488.6;⁷ see also U.S. ex rel.

⁶ Insofar as the complaint appears to equate "certification" with "accreditation," the parties' subsequent briefing primarily refers to TJC's accreditation services. The court understands the references in the complaint to TJC's "certification" program as encompassing "accreditation" services.

⁷ Prior to 2010, TJC's hospital accreditation program was guaranteed statutory "deeming authority" that did not require Centers for Medicare and Medicaid Services ("CMS") review and approval. Congress revoked this status when it amended Section 1865 of the Social Security Act, 42 U.S.C. § 1395bb. See Medicare Improvements for Patients and Providers Act of 2008,

Ortega v. Columbia Healthcare, Inc., 240 F. Supp. 2d 8, 19 (D.D.C. 2003) (“[W]hile [TJC] accreditation automatically confers eligibility to participate in Medicare, it is not a prerequisite.”). Courts may also rely on TJC accreditation in determining whether HCOs complied with Medicaid’s standard of care. See Evelyn V. v. Kings Cty. Hosp. Ctr., 819 F. Supp. 183, 189 (E.D.N.Y. 1993) (citing Woe by Woe v. Cuomo, 729 F.2d 96, 106 (2d Cir. 1984)) (“Although courts generally accord considerable deference to the findings of the Joint Commission, its accreditation serves only as ‘prima facie’ evidence of compliance with Medicaid standards.”).

Many states rely on TJC’s accreditation process to help evaluate HCOs. For instance, West Virginia exempts hospitals from periodic licensure inspections if they received accreditation by TJC or the American Osteopathic Association in

Pub. L. 110-275, July 15, 2008, 122 Stat. 2494. Subsequently, TJC was required to first apply to CMS for renewal of its hospital deeming authority before the Secretary of the Department of Health and Human Services would recognize it as a national accreditation body for hospitals that participate in the Medicare or Medicaid programs. TJC’s status was last approved in July 2020, effective until July 15, 2022. See Application From the Joint Commission for Continued Approval of its Hospital Accreditation Program, 85 Fed. Reg. 43,582 (July 17, 2020); see also 42 C.F.R. § 488.4. TJC is one of several accreditation organization that has received statutory “deeming authority” status. See FY 2015 Report to Congress (RTC): Review of Medicare’s Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program, 2016 WL 1238751, at *8-15.

the preceding year. W. Va. Code § 16-5B-5a;⁸ Compl. ¶ 19. Most states contain similar provisions that allow hospitals that have received accreditation from TJC, or another nationally recognized accrediting organization, to receive exemptions from the state's periodic licensure inspections.⁹

⁸ The statute provides that "[t]he state department of health and human resources shall grant an exemption from a periodic license inspection during the year following accreditation if a hospital applies by submitting evidence of its accreditation by the joint commission on accreditation of health care organizations . . . and submits a complete copy of the commission's accreditation report. W. Va. Code § 16-5B-5a. On March 5, 2020, the West Virginia legislature amended § 16-5B-5a to add language allowing hospitals to also submit evidence of accreditation by "any accrediting organization approved by the Centers for Medicare and Medicaid Services." 2020 W. Va. Legis. Serv. S.B. 767. The amended statute took effect on June 23, 2020.

⁹ These states include Alabama (Ala. Code § 22-21-24); Alaska (Alaska Stat. § 18.20.080); Arizona (Ariz. Rev. Stat. § 36-424); Arkansas (Ark. Code Ann. § 20-9-219); Colorado (Colo. Rev. Stat. Ann. § 25-3-102.1); Connecticut (Conn. Agencies Regs. § 19-13-D1a); Florida (Fla. Admin. Code Ann. r. 59A-3.253); Hawaii (Haw. Rev. Stat. Ann. § 321-14.5); Illinois (Ill. Admin. Code tit. 77, § 250.130); Indiana (Ind. Code Ann. §§ 16-21-2-13, 16-18-2-308.5; 2020 Ind. Legis. Serv. P.L. 156-2020 (H.E.A. 1096)); Iowa (Admin. Code r. 481-51.2(135B)); Kansas (Kan. Stat. Ann. § 65-429); Kentucky (Ky. Rev. Stat. Ann. § 216B.185); Louisiana (48 La. Admin. Code tit. 48, Pt I, § 9309); Maine (10-144 Me. Code R. Ch. 112, § 2); Maryland (Md. Code Ann., Health-Gen. §§ 19-301(b), 19-2302); Massachusetts (105 Mass. Code Regs. 130.202); Michigan (Mich. Comp. Laws Ann. § 333.20155); Minnesota (Minn. Stat. Ann. § 144.55); Missouri (Mo. Ann. Stat. § 197.100); Montana (Mont. Code Ann. § 50-5-103); Nebraska (175 Neb. Admin. Code Ch. 9, § 004.09); Nevada (Nev. Admin. Code § 449.310); New Hampshire (N.H. Rev. Stat. Ann. § 151:6-a); New Jersey (N.J. Admin. Code § 8:43G-2.5); New Mexico (N.M. Stat. Ann. § 24-1-5); New York (N.Y. Mental Hyg. Law § 31.08; N.Y. Comp. Codes R. & Regs. tit. 14, § 553.5); North Carolina (10A N.C. Admin. Code 13B.3106); North Dakota (N.D. Admin. Code 33-07-01.1-06); Ohio

TJC's wholly owned subsidiary, Joint Commission Resources, Inc. d/b/a Joint Commission International ("JCR"), is a not-for-profit organization formed in 1998 "that provides training, consulting, publications, and support for health care organizations seeking to comply with [TJC's] standards." Id. ¶ 15. In addition to publishing TJC's standards, JCR provides a supporting role to TJC as a consultant, educator, and "personal certification provider that administers examinations" at various test centers. Id. ¶¶ 18, 90. In 2015, JCR reported nearly \$60,000,000 in total revenue. Compl. ¶ 15.

II. Background

The complaint alleges that in December 2001, TJC collaborated with Purdue Pharma L.P. and its affiliates ("Purdue") and other opioid manufacturers to issue Pain Management Standards ("PM Standards"), as set forth in the accompanying "Comprehensive Accreditation Manual for

(Ohio Admin. Code 3701-59-03); Oregon (Or. Admin. R. 333-501-0015); Pennsylvania (28 Pa. Code § 101.62); Rhode Island (216 R.I. Code R. § 40-10-4.4); South Dakota (S.D. Codified Laws § 34-12-16); Tennessee (Tenn. Code Ann. § 68-11-210); Texas (25 Tex. Admin. Code § 133.101); Utah (Utah Admin. Code r. R432-3-3); Virginia (12 Va. Admin. Code § 5-410-140); Washington (Wash. Admin. Code § 246-320-016); and Wyoming (Wyo. Stat. Ann. § 35-2-907), plus the District of Columbia (D.C. Mun. Regs. tit. 22-B, § 2000). The court was unable to locate analogous statutory provisions regarding hospital licensure inspections for California, Delaware, Georgia, Idaho, Mississippi, Oklahoma, South Carolina, Vermont, or Wisconsin.

Hospitals: The Official Handbook," and "other related documents" as part of TJC's certification program. Compl. ¶¶ 1, 32. According to plaintiffs, the PM Standards and related materials "grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices, the result of which was often inappropriate provision of opioids with disastrous adverse consequences." Id. ¶ 1.

For instance, The Official Handbook and 2001 Standard RI.1.2.7¹⁰ instructs that HCOs "address[] care at the end of life" and that "[e]ffective pain management is appropriate for all patients, not just dying patients (see Standards RI.1.2.8 and P.E.1.4)." Compl. ¶¶ 33-34. The 2001 Standard RI.1.2.8 further provides that "[p]atients have the right to appropriate assessment and management of pain" and requires that an HCO "plans, supports, and coordinates activities and resources to assure the pain of all patients is recognized and addressed appropriately." Id. ¶ 35. The first example of "Implementation of Standard RI.1.2.8," in The Official Handbook provides, "Pain is considered the 'fifth' vital sign in the hospital's care of patients" along with, in no

¹⁰ While not expressly explained in the complaint or briefing, the court understands that "RI" and similar abbreviations refer to the specific chapters or categories in The Official Handbook. See Compl. ¶ 32.

particular order of importance, temperature, pulse, respiration, and blood pressure. Id. ¶ 36. The 2001 Standard P.E.1.4 adds, "Pain is assessed in all patients." For example, "All patients at admission are asked the following screening or general question about the presence of pain: Do you have pain now?" Id.

That same year, TJC teamed with the National Pharmaceutical Council, Inc. ("NPC"), a group that includes opioid manufacturers and distributors, to publish a monograph titled, "Pain: Current Understanding of Assessment, Management, and Treatments" ("2001 NPC Monograph"). Compl. ¶¶ 41-42. The 2001 NPC Monograph notes "the high prevalence of pain, continuing evidence that pain is undertreated, and a growing awareness of the adverse consequences of inadequately managed pain." Id. ¶ 43. Under "Common Misconceptions About Pain," it categorizes "use of opioids in patients with pain will cause them to become addicted" as an "incorrect belief." Id. ¶ 47.

TJC also produced a 2001 monograph ("2001 TJC Monograph") titled, "Improving the Quality of Pain Management Through Measurement and Action," which states, "Some clinicians have inaccurate and exaggerated concerns about addiction, tolerance and risk of death. This attitude prevails

despite the fact there is no evidence that addiction is a significant issue when persons are given opioids for pain control." Id. ¶¶ 45-46. Both 2001 Monographs from NPC and TJC add, "The two monographs were produced under a collaborative project between NPC and [TJC] and are jointly distributed." Id. ¶ 45.

Between 2000 and 2002, TJC also sponsored a series of educational programs on its PM Standards "devoted, in part, to correcting, in TJC's words, 'clinicians' misconceptions about pain treatments' including 'an exaggerated fear of addiction resulting from use of opioids.'" Compl. ¶ 51. Also, from 2001 to 2002, "Purdue funded a series of nine programs throughout the country to educate hospital physicians and staff on how to comply with [TJC's PM Standards] for hospitals."

Id. ¶ 53.

In 2003, as part of a collaborative project between NPC and TJC, TJC published "Improving the Quality of Pain Management Through Measurement and Action" ("2003 TJC Monograph") and NPC published "Pain: Current Understanding of Assessment, Management, and Treatments" ("2003 NPC Monograph"). Compl. ¶¶ 60-61. The 2003 TJC Monograph states, "Clinicians' misconceptions about pain treatments could include an exaggerated fear of addiction resulting from use of opioids."

Id. ¶ 62. Citing "[r]ecent court cases concerning patients with unrelieved pain," it notes that "[s]crutiny of clinician practice includes not only the investigation of the overprescription of opioids but increasingly the study of cases of underprescribing." Id. It also states that "promoting the idea that there is a high risk of addiction when opioids are taken for pain relief" is "faulty and outdated." Id.

As one of its "educational interventions," the 2003 TJC Monograph also provided "a laminated trifold pocket card . . . to all staff for quick reference to the World Health Organization analgesic ladder, opioid dosing, and opioid/coanalgesic equivalency tables." Compl. ¶¶ 65-66. The ladder provides that if pain occurs, drugs should be administered in the following order: "nonopioids (aspirin and paracetamol [also known as acetaminophen]); then, as necessary, mild opioids (codeine); then strong opioids such as morphine, until the patient is free of pain." Id. Plaintiffs allege that insofar as the trifold pocket card endorsed and promoted the goal of "free of pain," it "contributed not only to the widespread prescription of opioids, but also to opioid doses strong enough to deliver freedom from pain." Id. ¶¶ 67-68.

Plaintiffs allege that TJC still enforces the PM Standards "with minor modifications . . . to this day."

Compl. ¶ 1-2. The 2009 PM Standards again instructs, "The hospital assesses and manages the patient's pain." Id. ¶ 71. According to plaintiffs, "the plain wording of this Standard requires assessing pain in every patient, no matter how presented." Id. ¶ 72. In 2011, TJC and JCR published an article in The Source, which provides for "Joint Commission Compliance Strategies" and describes pain as "The Fifth 'Vital Sign.'" Id. ¶ 74.

In 2012, Janssen Pharmaceuticals, an opioid manufacturer, provided funding for JCR's publication of a monograph titled, "Pain Management: A Systems Approach to Improving Quality and Safety" ("2012 JCR Monograph"), which contained a "toolkit" for "pain management strategies." Id. ¶¶ 75-76. In a section of the toolkit titled "What You Should Know about Pain Management," it instructs patients, "Tell your doctor or nurse about your fears," but assures them that "[s]tudies show that addiction is unlikely. This is especially true if the patient has never been addicted." Id. ¶¶ 77-78. Regarding fears of "tolerance," it concludes, "You may need more medicine or a different kind of medicine to control your pain. Id. ¶ 78.

TJC issued a "Clarification to Standard PC.01.02.07" in November 2014, but still left "opioids" as one of the

"pharmacologic and nonpharmacologic strategies" that "have a role in the management of pain." Compl. ¶¶ 79-80. In 2016, TJC reexamined the PM Standards and reissued new Standards in July 2017 to take effect in January 2018. Id. ¶ 86. The revised Standards include changes to the pain assessment process and changes to promote safe opioid use during and after hospitalization. Id. ¶ 87. However, plaintiffs claim TJC "exhibits no urgency in implementing the new Standards" and that the new Standards still fail to acknowledge "that some patients who do not fall into known risk categories . . . are highly vulnerable to opioid addiction" and fail to address "the unique risks of opioid prescriptions to pregnant patients." Id. ¶¶ 5-7.

In response to critiques of the PM Standards, Dr. David Baker, Executive Vice President of TJC, argues in The Joint Commission's Pain Standards: Origins and Evolution (2017) ("Origins and Evolution") that "[m]any doctors were afraid to prescribe opioids despite a widely-cited article suggesting that addiction was rare when opioids were used for short-term pain," and "that in 'the Clarion Call for a Different Approach to Improve Assessment and Treatment of Pain,' the President of the American Pain Society 'emphasized the conventional wisdom of the day that therapeutic use of opiate analgesics rarely results in

addiction.'" Compl. ¶ 48. Dr. Baker admits, however, that the "widely-cited article" was "a single publication that lacked detail about how the study was done." Id. Indeed, this article/publication was only a "five-sentence letter to the editor of the New England Journal of Medicine" in 1980.

Id. ¶ 49 (citing Jane Porter & Hershel Jick, Addiction Rare in Patients Treated with Narcotics, 302 N. Engl. J. Med. 123 (1980)).

On April 13, 2016, Physicians for Responsible Opioid Prescribing sent a letter to the President and CEO of TJC, urging TJC to reexamine the PM Standards and "affirming that treatment strategies may include non-pharmacological approaches." Compl. ¶ 82. The letter emphasizes as follows:

"Pain is a symptom, not a vital sign. Blood pressure, heart rate, respiratory rate and temperature are vital signs that can be objectively measured. Pain is only one of many distressing symptoms that patients can experience and to which health care professionals must be attentive Mandating routine pain assessments for all patients in all settings is unwarranted and can lead to overtreatment and overuse of opioid analgesics.

Id. (emphasis in original). The letter further argues that the PM Standards "foster dangerous pain control practices" and that the U.S. "experienced a sharp rise in prescriptions for opioid analgesics following the introduction of the Pain Management Standards." Id.

Plaintiffs allege that "[w]hile [TJC's] Pain Management Standards never overtly required opioid treatments, the expectation that every patient, no matter how presented, should be asked about pain vastly expanded the market for opioid treatments." Compl. ¶ 56. Plaintiffs contend that the monographs, educational materials, trainings, and direct association with opioid manufacturers "signaled that the best way to meet the [TJC's] Pain Management Standards was to treat more and more patients with opioids." Id. ¶ 56.

Moreover, plaintiffs allege that "[b]ecause of its certification program, [TJC] wields enormous power over health care organizations." Compl. ¶ 16. In effect, "[h]ospitals that routinely treat the residents of Plaintiffs were required to follow" the PM Standards to ensure their continued operation. Id. ¶ 3.

In their three-count complaint filed on November 2, 2017, plaintiffs contend that defendants could have "prevented or curtailed" the opioid crisis. Compl. ¶ 88. They argue that if defendants had acted to prevent the overprescribing of opioid pharmaceuticals, municipalities would not have suffered harm.

Pursuant to Rules 23(b)(2) and 23(b)(3) of the Federal Rules of Civil Procedure, plaintiffs bring this action on behalf of the following nationwide class: "All cities and towns in the

United States of America that contain or whose citizens are treated at a health care organization certified by [TJC].” Id. ¶ 125. The statewide subclass includes: “All cities and towns in the State of West Virginia that contain or whose citizens are treated at a health care organization certified by [TJC].” Id. ¶ 126.

Under Count I, the Municipalities bring claims of negligence, gross negligence, and reckless and willful conduct alleging that defendants owed a duty of care to the municipalities and breached it by promulgating the Pain Management Standards and engaging “in a misinformation campaign that grossly misrepresented the safety of prescription opioids.” Compl. ¶ 144. Under Count II, plaintiffs claim that defendants were unjustly enriched when they accepted funding from pharmaceutical companies to promote the PM Standards that “failed to recognize the dangerous and addictive nature of opioids.” Id. ¶ 150. The plaintiffs “seek the equitable relief of declaratory judgment, injunction, and remediation” under Count III. Id. ¶ 159.

Count III asks for a declaration that TJC must refrain from promulgating, utilizing, or enforcing PM Standards in certifying HCOs until such PM Standards set forth by TJC (a) “discourage opioid treatment for patients except as a

treatment of last resort," (b) disclose that minors and the unborn are at greater risk for addiction; and (c) include the following "corrective language" based on a March 2016 statement issued by the Centers for Disease Control and Prevention:

The science of opioids for chronic pain is clear: For the vast majority of patients, the known, serious, and too-often-fatal risks far outweigh the unproven and transient benefits. Overall, 1 of every 550 patients started on opioid therapy died of opioid-related causes a median of 2.6 years after the first opioid prescription; the proportion was as high as 1 in every 32 among patients receiving doses of 200 [morphine milligram equivalents] or higher. We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.

Compl. ¶¶ 4, 157.a.

Plaintiffs further request a declaration under Count III requiring JCR to (a) distribute the same "corrective language" to all HCOs that have received consulting, training, certifications, and assessments from defendants, or received publications related to the Standards, and (b) notify HCOs that information contained in certain publications they received inaccurately disclosed the risks of pain medication and that such publications should no longer be distributed. Id. ¶ 158. Both declarations would also state that each defendant may no longer (1) accept funding from pharmaceutical companies related to any standards used to certify HCOs, (2) jointly produce educational materials or programs with pharmaceutical companies

used to certify HCOs; and (3) distribute information produced by pharmaceutical companies related to standards used to certify HCOs. Id. ¶¶ 157–58.

On January 29, 2018, TJC filed a joint motion to dismiss, or in the alternative, to strike class action allegations. See TJC's Mot. Dismiss & Mot. Strike, ECF No. 19 ("ECF No. 19"). TJC argues that (1) plaintiffs lack Article III standing, (2) Count I fails for lack of duty (3) the complaint fails to meet federal pleading standards because the harm is too remote and intervening acts break the chain of causation, (4) plaintiffs cannot recover the costs of public services, (5) plaintiffs cannot bring a claim of unjust enrichment under Count II because they lack a right to the funds they seek to recover, (6) plaintiffs do not state a claim under Count III, which also constitutes an unconstitutional prior restraint on speech, (7) plaintiffs' claims are preempted by West Virginia law, (8) the tort claims are barred by the statute of limitations, and (9) in the alternative, the court should strike plaintiffs' class action allegations. See ECF No. 20.

JCR filed a separate motion to dismiss on the same date and incorporated by reference these same arguments, adding that it did not owe plaintiffs a duty as publisher of the PM Standards. See JCR's Mot. Dismiss, ECF No. 21. After plaintiffs

filed a memorandum in opposition to these motions, defendants filed a joint reply.¹¹ Defendants also filed a motion for scheduling order for submission of amicus curiae briefs. See Defs.' Mot. Scheduling Order for Submission of Amicus Curiae Brs., ECF No. 35 ("ECF No. 35"). Plaintiffs filed a motion in opposition and defendants filed a reply.¹²

Attached as Exhibit 1 to defendants' reply to plaintiffs' memorandum in opposition to the motion to dismiss is a list of new facts plaintiffs included in the "Facts" section of their memorandum. See Improper Facts Asserted by Plaintiffs in Opposition Brief, ECF No. 32-1; ECF No. 28 at 2-11. For example, plaintiff's memorandum alleges that defendants' "knew that they were exposing virtually every person in America to opioid treatment." ECF No. 28 at 5. Like the rest of the allegations in this "Facts" section, plaintiffs base this assertion on an allegation contained in the complaint, namely, that "the market for opioids was enormous, but largely untapped

¹¹ See Pls.' Mem. Opp. Mot. Dismiss & Mot. Strike, ECF No. 28 ("ECF No. 28"); Defs.' Reply to Pls.' Mem. Opp. Mot. Dismiss & Mot. Strike, ECF No. 32 ("ECF No. 32").

¹² See Pls.' Mem. Opp. Mot. Scheduling Order for Submission of Amicus Curiae Brs., ECF No. 36 ("ECF No. 36"); Defs.' Reply Supp. Mot. Scheduling Order for Submission of Amicus Curiae Brs., ECF No. 37 ("ECF No. 37").

because health care providers feared turning patients into addicts." See id. at 5 n.18 (quoting Compl. ¶ 44).

Plaintiffs did not move to amend their complaint to include these new allegations. Consequently, the court will only consider the allegations contained in the complaint itself for the purposes of resolving the pending motions to dismiss. Occupy Columbia v. Haley, 738 F.3d 107, 116 (4th Cir. 2013) ("In resolving a motion pursuant to Rule 12(b)(6) or Rule 12(c), a district court cannot consider matters outside the pleadings without converting the motion into one for summary judgment."); Imagine Medispa, LLC v. Transformations, Inc., 999 F. Supp. 2d 873, 879 (S.D.W. Va. 2014) (refusing to consider new allegations contained in response to motion to dismiss where plaintiffs had not moved to amend their complaint).

III. Motion to Dismiss

A. Legal Standard

Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Rule 12(b)(6) correspondingly provides that a pleading may be dismissed when there is a "failure to state a claim upon which relief can be granted." To survive a motion to dismiss, a pleading must

recite "enough facts to state a claim to relief that is plausible on its face." Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). In other words, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555 (citation omitted).

"In resolving a motion pursuant to Rule 12(b)(6)[,] a district court cannot consider matters outside the pleadings without converting the motion into one for summary judgment." Occupy Columbia, 738 F.3d at 116 (citing Fed. R. Civ. P. 12(d)). "A court may, however, consider a 'written instrument' attached as an exhibit to a pleading, 'as well as [documents] attached to the motion to dismiss, so long as they are integral to the complaint and authentic.'" Id. (alteration in original) (internal citation omitted) (quoting Fed. R. Civ. P. 10(c) and Phillips v. Pitt Cty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009)).

A district court's evaluation of a motion to dismiss is underlain by two principles. First, the court "must accept as true all of the factual allegations contained in the [pleading]." Erickson v. Pardus, 551 U.S. 89, 94 (2007) (citing Twombly, 550 U.S. at 555-56). Such factual allegations should

be distinguished from "mere conclusory statements," which are not to be regarded as true. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) ("[T]he tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions."). Second, the court must "draw[] all reasonable factual inferences . . . in the [nonmovant's] favor." Edwards v. City of Goldsboro, 178 F.3d 231, 244 (4th Cir. 1999).

Plaintiffs have the burden of establishing standing and "must 'clearly . . . allege facts demonstrating' each element" at the pleading stage. Spokeo, Inc. v. Robins, 136 S. Ct. 1540, 1547 (2016) (quoting Warth v. Seldin, 422 U.S. 490, 518 (1975)). "When standing is challenged on the pleadings, we accept as true all material allegations of the complaint and construe the complaint in favor of the complaining party." David v. Alphin, 704 F.3d 327, 333 (4th Cir. 2013). "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we 'presum[e] that general allegations embrace those specific facts that are necessary to support the claim.'" Lujan v. Defenders of Wildlife, 504 U.S. 555, 561 (1992) (alteration in original) (quoting Lujan v. Nat'l Wildlife Fed'n, 497 U.S. 871, 889 (1990)).

B. Article III Standing

Article III of the Constitution imposes limits on who may bring suits in federal court. To present a case or controversy under Article III:

[A] plaintiff must show (1) it has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs. (TOC), Inc., 528 U.S. 167, 180-81 (2000) (citing Defenders of Wildlife, 504 U.S. at 560-561).

a. Injury in Fact

Defendants argue that the claim is not "concrete and particularized" because plaintiffs have only alleged harm related to the "increased" costs of providing public services. ECF No. 20 at 29. As plaintiffs correctly point out, a city can have standing to bring a claim based on "increased need for city services." ECF No. 28 at 30 (quoting City of Los Angeles v. JPMorgan Chase & Co., No. 2:14-CV-04168-ODW, 2014 WL 6453808, at *4 (C.D. Cal. Nov. 14, 2014)); see also Gladstone Realtors v. Vill. of Bellwood, 441 U.S. 91, 110-11 (1979) ("A significant reduction in property values directly injures a municipality by

diminishing its tax base, thus threatening its ability to bear the costs of local government and to provide services."); Air Evac EMS, Inc. v. Cheatham, 910 F.3d 751, 760 (4th Cir. 2018) ("[F]inancial harm is a classic and paradigmatic form of injury in fact"). Inasmuch as plaintiffs allege an injury stemming from the costs of providing municipal services in response to the opioid crisis, they satisfy the injury in fact requirement.

b. Fairly Traceable

Next, plaintiffs must satisfy the "fairly traceable" requirement under Article III, which "ensures that there is a genuine nexus between a plaintiff's injury and a defendant's alleged illegal conduct." Friends of the Earth, Inc. v. Gaston Copper Recycling Corp., 204 F.3d 149, 161 (4th Cir. 2000). It does not require a showing of proximate cause. See Libertarian Party of Virginia v. Judd, 718 F.3d 308, 316 (4th Cir. 2013). Still, "[w]hile the defendant's conduct need not be the last link in the causal chain, the plaintiff must be able to demonstrate that the alleged harm was caused by the defendant, as opposed to the 'independent action of some third party not before the court.'" Air Evac EMS, 910 F.3d at 760 (quoting Frank Krasner Enters., Ltd. v. Montgomery Cty., 401 F.3d 230, 234 (4th Cir. 2005)).

To support their causation argument, defendants rely on three cases where "courts have dismissed claims against gun manufacturers, cold medicine manufacturers, and alcohol distributors and distillers." ECF No. 20 at 30; ECF No. 32 at 19-20. None of these cases defeat Article III standing here. In City of Philadelphia v. Beretta U.S.A. Corp., the district court found that the civic organizations suing gun manufacturers lacked Article III standing when it was the organizations' members rather than the organizations themselves that suffered harm. 126 F. Supp. 2d 882, 895 n.9 (E.D. Pa. 2000), aff'd, 277 F.3d 415 (3d Cir. 2002). Yet, the Third Circuit opinion affirming City of Philadelphia v. Beretta U.S.A. Corp. makes clear that both the district court and the circuit court in that case dismissed the city's claims on unrelated grounds and that, while the civic organizations lacked standing, "the City's Article III standing [was] not questioned or in doubt." 277 F.3d 415, 420 n.3-4 (3d Cir. 2002).

Likewise, Ashley County v. Pfizer, Inc., the cold medicine manufacturing case, only addressed causation – not standing – and only did so under the framework of proximate cause. 552 F.3d 659, 666 (8th Cir. 2009). On the other hand, Bertovich v. Advanced Brands & Importing, Co. applied West Virginia's analogous standing principles to determine whether

the plaintiff parents sufficiently pled causation against alcohol companies and trade associations responsible for distributing and marketing alcohol to their underage children. No. 5:05CV74, 2006 WL 2382273, at *9 (N.D.W. Va. Aug. 17, 2006) (citing Findley v. State Farm Mut. Auto. Ins. Co., 576 S.E.2d 807, 821 (W. Va. 2002)). The court dismissed the complaint under Rule 12(b)(6) because the parents' injuries were derivative to those of their children and causation was not otherwise sufficiently pled. Id. at *9-10. The decision did not address Article III standing.

Here, the complaint alleges that defendants caused harm to plaintiffs in the form of increased health care, insurance, social services, emergency, and other costs. Compl. ¶¶ 89-124. These harms are not derivative of third parties absent from this case, such as city residents. Moreover, plaintiffs explicitly link the alleged misinformation in the PM Standards to the rise of the opioid epidemic that sparked these costs. For instance, plaintiffs quote from the April 13, 2016 letter from Physicians for Responsible Opioid Prescribing which, as earlier quoted, wrote to the President and CEO of TJC that "[m]andating routine pain assessments for all patients in all settings is unwarranted and can lead to overtreatment and overuse of opioid analgesics." Id. ¶ 82.b.

The letter continued to warn that the standards found in the PM Standards "interfere with primary disease management" and "foster dangerous pain control practices, the endpoint of which is often the inappropriate provision of opioids with disastrous adverse consequences for individuals, families and communities." Id. ¶ 82.a, e. Insofar as Bertovich and other courts have dismissed similar claims for failing to sufficiently plead proximate causation, the court will address those arguments separately from the standing inquiry.

c. Redressability

Finally, defendants argue that the costs and expenses incurred by plaintiffs are not redressable, citing two Fourth Circuit cases that denied standing where "an independent third party, who was not a party to the lawsuit, stood between the plaintiff and the challenged actions." Frank Krasner, 401 F.3d at 235 (citing Burke v. City of Charleston, 139 F.3d 401 (4th Cir. 1998)).

First, Frank Krasner Enterprises, Ltd. v. Montgomery County addressed whether a plaintiff gun show promoter and gun show exhibitor had standing to challenge a county law that prohibited funding of organizations that allow the display and sale of guns at their facilities. 401 F.3d 230, 232-33, 236 (4th Cir. 2005). As a result of the law's funding restrictions,

the agricultural center ("Ag Center"), a third party not before the court, stopped hosting plaintiffs' gun shows. Id. The court found that even if the plaintiffs prevailed and the law was struck down, it "could not compel the Ag Center to rent space to [the plaintiff gun show promoter] (nor, crucially, could we even direct the County to subsidize the Ag Center in the future.)" Id. at 236. In Burke v. City of Charleston, the court held that an artist challenging the constitutionality of a city ordinance that banned the display of one of his murals lacked standing because his requested relief - displaying the mural - was speculative when the painter had sold his rights to the mural and the subsequent owner was free to paint over it at any time. 139 F.3d 401, 406-07 (4th Cir. 1998).

Defendants extend these cases to mean plaintiffs' claims are not redressable because "independent factors" stand in the way of recovery. First, defendants cite the free public services doctrine as limiting plaintiffs' ability to recover damages. In short, defendants argue that the claims raised in the complaint are not redressable because the doctrine would, if applied here, bar plaintiffs from recovering costs, incurred by providing public services related to the opioid crisis, from the tortfeasors whose conduct created the need for services. See City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co., 719

F.2d 322, 323 (9th Cir. 1983) (outlining free public services doctrine).¹³ Neither Frank Krasner nor Burke mention or pertain to the free public services doctrine. Whether the free public services doctrine and economic loss rule bar plaintiffs' substantive negligence claims go to the merits rather than the jurisdiction of this court to hear this suit.

Citing Frank Krasner and Burke, defendants also assert that even if the PM Standards change, the court cannot stop doctors and pharmacists from overprescribing and overdistributing opioids or patients from illegally selling the drugs. Defendants also note that the State Department of Health can always dictate different standards of treatment.

Again, the principles applied in these cases do not preclude redressability here. The complaint does not request or require the court to take any action against these third parties. Plaintiffs' ability to obtain relief does not "depen[d] on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate

¹³ Although defendants originally pointed to the "economic loss rule" and free public services doctrine together as intervening factors preventing plaintiffs from obtaining the relief sought, defendants dropped the reference to the economic loss doctrine in their reply brief's redressability arguments. In any case, the economic loss rule only pertains to plaintiffs' negligence claims and will be analyzed accordingly in Section III.C.a. See Aikens v. Debow, 541 S.E.2d 576 (W. Va. 2000).

discretion the courts cannot presume either to control or to predict." Frank Krasner, 401 F.3d at 235 (quoting Defenders of Wildlife, 504 U.S. at 562). If plaintiffs succeed in their claims, the court has the power to grant them monetary, declaratory, or injunctive relief without relying on the intervention of third parties not before the court. Moreover, the existence of other factors impacting the opioid crisis does not preclude standing. Plaintiffs need only demonstrate "a non-speculative likelihood that the injury would be redressed by a favorable judicial decision," which they have done here. Frank Krasner, 401 F.3d at 234. Because plaintiffs have demonstrated that they have Article III standing, the court now turns to the merits.

C. Count I: Negligence, Gross Negligence, Reckless and Willful Conduct

Under Count I, plaintiffs raise claims of negligence, gross negligence, and reckless and willful conduct under both West Virginia and Illinois law. Compl. ¶ 143. While Illinois law may govern the claims of the nationwide class upon class certification, both parties agree that the named plaintiffs' claims fall under West Virginia's governing negligence standard.

To prevail on a claim of negligence, plaintiffs must show that defendants "[1] owed the plaintiff some duty of care;

[2] that by some act or omission the defendant breached that duty; [3] and that the act or omission proximately caused some injury to the plaintiff [4] that is compensable by damages."

Hersh v. E-T Enterprises, Ltd. P'ship, 752 S.E.2d 336, 341 (W. Va. 2013) superseded by statute on other grounds as stated in Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cty., 773 S.E.2d 627 (W. Va. 2015).

"In order to establish a prima facie case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff." Syl. Pt. 1, Parsley v. Gen. Motors Acceptance Corp., 280 S.E.2d 703, 706 (W. Va. 1981). "Questions of negligence, due care, [and] proximate cause . . . present issues of fact for jury determination when the evidence pertaining to such issues is conflicting or where the facts, even though undisputed, are such that reasonable men may draw different conclusions from them." Syl. Pt. 5, Hatten v. Mason Realty Co., 135 S.E.2d 236 (W. Va. 1964). However, the "determination of whether plaintiff is owed a duty of care by a defendant must be rendered by the court as a matter of law." Aikens v. Debow, 541 S.E.2d 576, 578 (W. Va. 2000).

As a preliminary matter, the parties dispute the requisite elements necessary to establish a duty. Defendants

argue that under Aikens v. Debow, 541 S.E.2d 576 (W. Va. 2000), plaintiffs must establish three elements before a court will impose a duty: "(1) privity or a special relationship between defendant and plaintiff; (2) foreseeable harm; and, (3) policy considerations." ECF No. 32 at 3 (citing 541 S.E.2d at 590). While acknowledging the latter two elements, plaintiffs argue that the first Aikens requirement only applies to cases of purely economic loss under the so-called economic loss doctrine. ECF No. 28 at 17. The court will address each argument in turn.

a. Economic Loss Doctrine: Privity of Contract and Special Relationships

In Aikens, the West Virginia Supreme Court of Appeals held as follows:

[W]e conclude that an individual who sustains purely economic loss from an interruption in commerce caused by another's negligence may not recover damages in the absence of physical harm to that individual's person or property, a contractual relationship with the alleged tortfeasor, or some other special relationship between the alleged tortfeasor and the individual who sustains purely economic damages sufficient to compel the conclusion that the tortfeasor had a duty to the particular plaintiff and that the injury complained of was clearly foreseeable to the tortfeasor.

541 S.E.2d at 589 (emphasis added). The court emphasized that its holding "applies strictly to plaintiffs alleging purely economic loss from an interruption in commerce caused by

another's negligence" and does not affect claims of "medical monitoring, negligent infliction of emotional distress cases, or nuisance," which may lack physical injury to claimant or his or her property. Id. at 591.

Aikens adopted this economic loss rule, in part, to "provid[e] a barrier against limitless liability" and to prevent "chain-of-reaction" claims. 541 S.E.2d at 590-92. The case involved an accident where a truck driver struck a highway bridge, which, as a result of the bridge's closure, led the owner of a nearby motel/restaurant to suffer decreased revenues. Id. at 579. The court found that the motel/restaurant owner could not recover inasmuch as he suffered no physical damage, had no contract with the truck driver or his employer, and lacked an otherwise special relationship with the defendants. Id. at 580. The court emphasized "the danger of expanding the concept of duty in tort to include economic interests and consequent exposure of defendants 'to a liability in an indeterminate amount for an indeterminate time to an indeterminate class.'" Id. at 581 (quoting Ultramares Corp. v. Touche, 174 N.E. 441, 444 (N.Y. 1931)).

Plaintiffs argue that the doctrine is inapplicable because they do not allege (1) "purely economic loss" inasmuch as the complaint alleges "disruptions to quality of life" and

community blight (2) losses stemming from "an interruption in commerce," or (3) injury to "property of a third person." ECF No. 28 at 17, 23-24. Yet, with respect to damages, the complaint itself categorizes its losses as falling under "significant economic damages," alleging:

[Plaintiffs] have suffered significant economic damages, including, but not limited to, increased health care costs, insurance and self-insurance costs, health services costs, costs related to responding to and dealing with opioid-related crimes and emergencies, additional first responders, first responder and building department overtime, remediation of dilapidated and fire-damaged properties, criminal vagrancy, and other significant public safety costs and disruptions to quality of life and commerce.

Compl. ¶ 31 (emphasis added).

Alleged injuries do not qualify as "purely" economic loss when they also include attendant damage to a claimant's property or person. See Aikens, 541 S.E.2d at 589; see generally S. California Gas Leak Cases, 441 P.3d 881, 885 (Cal. 2019) (quoting Dan B. Dobbs, An Introduction to Non-Statutory Economic Loss Claims, 48 Ariz. L. Rev. 713, 713 (2006) (defining "purely economic loss" as "pecuniary or commercial loss that does not arise from actionable physical, emotional or reputational injury to persons or physical injury to property.")); Restatement (Third) of Torts: Liab. for Econ. Harm § 1 cmt. c (2019) (defining "[a]n economic loss or injury" as "a

financial loss not arising from injury to the plaintiff's person or from physical harm to the plaintiff's property"). In Sigman v. CSX Corp., for example, this court found that allegations of "real and personal property damage" and allegations that "harmful chemicals polluted and contaminated their food and water supplies" were sufficient to withstand the economic loss doctrine at the motion to dismiss stage. No. CV 3:15-13328, 2016 WL 2622007, at *2 (S.D.W. Va. May 5, 2016); see also Good v. Am. Water Works Co., No. CIV.A. 2:14-01374, 2015 WL 3540509, at *3-4 (S.D.W. Va. June 4, 2015) (declining to dismiss claims under economic loss doctrine where contaminated water allegedly "damaged Plaintiffs' property by necessitating the flushing or replacement of pipes, water heaters and other appliances").

Courts also look to the proprietary interests affected in the context of municipalities bringing claims to recover for governmental services and related costs. In City of Chicago v. Beretta U.S.A. Corp., the Supreme Court of Illinois found that damages sought by plaintiff municipalities, including compensation for law enforcement and medical services expenditures incurred in response to gun violence were "'solely economic damages' in the sense that they represent costs incurred in the absence of harm to a plaintiff's person or property." 821 N.E.2d 1099, 1143 (Ill. 2004).

In one of the complaints against pharmaceutical manufacturers (including Purdue), distributors and retail pharmacies in the multidistrict litigation ("MDL") before the Northern District of Ohio, municipal plaintiffs also alleged "economic damages including, but not limited to, significant expenses for police, emergency, health, prosecution, corrections, rehabilitation, and other services." In re National Prescription Opiate Litigation, No. 1:18-OP-45090, 2018 WL 4895856, at *1, n.1-3, *27 (N.D. Ohio Oct. 5, 2018), report and recommendation adopted in relevant part, No. 1:17-MD-2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018) (ruling on the claims asserted in The County of Summit, Ohio v. Purdue Pharma L.P., Case No: 18-OP-45090 (N.D. Ohio filed Jan. 22, 2018)) [hereinafter Summit County]. The court in Summit County, one of the "bellwether" cases selected by the Northern District of Ohio, declined to apply the economic loss rule to the negligence claim without further discovery, reaching this conclusion after finding that the plaintiff municipalities had already plausibly established the existence of a duty and had also "facially pled damages to their proprietary interests." Id. at *41. That ruling was relied on repeatedly in subsequent rulings denying

motions to dismiss negligence claims raised by other bellwether plaintiffs.¹⁴

By contrast, the Northern District of Ohio later granted a motion to dismiss a Michigan county's negligence claim based on Michigan law's distinction between economic losses and physical injury to person or property. In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2020 WL 2090355, at *19 (N.D. Ohio Apr. 30, 2020) (hereinafter Monroe County). The municipal plaintiff in Monroe County sought damages for injuries similar to those alleged in the present case, such as the cost of "treatment services, emergency visits, medical care, treatment for related illnesses and accidents, lost productivity . . . , increased law enforcement and judicial expenditures, increased prison and public works expenditures, increased substance abuse

¹⁴ See In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2019 WL 3737023, at *6-9 (N.D. Ohio June 13, 2019) (finding that bellwether Indian Tribes adequately alleged negligence and unjust enrichment, among other claims, against distributors, pharmacies, and manufacturers); In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2020 WL 871539, at *25-27, *32-33 (N.D. Ohio Feb. 21, 2020) (finding that private third-party payors adequately alleged negligence and unjust enrichment, among other claims); In re Nat'l Prescription Opiate Litig., No. 1:17-MD-2804, 2020 WL 1669655, at *27-28, *31-33 (N.D. Ohio Apr. 3, 2020) (finding that hospital adequately alleged negligence and unjust enrichment, among other claims, against distributors, pharmacies, and manufacturers of opioids); In re Nat'l Prescription Opiate Litig., No. 18-OP-45332, 2020 WL 1986589, at *9-12 (N.D. Ohio Apr. 27, 2020) (denying motion to dismiss negligence and unjust enrichment claims (among others) of Broward County, Florida).

treatment and diversion plan expenditures, lost economic activity, and lost reputation and good will." 2020 WL 2090355, at *19. The court dismissed the negligence claim, reasoning that "the County's alleged injuries are not the type of 'physical injury to person or property,' as opposed to 'economic' injury, required by Michigan law." Id. In reaching that conclusion, the Northern District of Ohio relied on Henry v. Dow Chemical Co., which held that "a plaintiff must demonstrate a present physical injury to person or property in addition to economic losses that result from that injury in order to recover under a negligence theory." 701 N.W.2d 684, 690 (Mich. 2005) (emphasis in original).

Here, plaintiffs cite no case that supports the proposition that "community blight" and "disruptions to quality of life" are non-economic damages. The disruptions to quality of life mentioned in the complaint include "the deterioration of neighborhoods," "abandoned houses," and "dangerous environmental pollution, including used needles" stemming from opioid addicts. Compl. ¶ 117. Plaintiffs allege that they bear the increased costs of removing residents of abandoned housing, repairing or bulldozing the abandoned property, and "remediating the environmental pollutants." Id. ¶ 117. The complaint continues that "deteriorating neighborhoods, criminal vagrancy, and overt

drug dealing, has hampered the Municipalities' efforts to attract new businesses and sources of tax revenue and employment." Id. ¶ 120. However, none of these allegations relate to damage to plaintiffs' person or proprietary interest. Taking over abandoned property and the other types of harm alleged do not amount to damage to one's property or proprietary interest. Cleaning up used needles may constitute a hazard for the police officers who collect them and are injured, but only an economic loss to the city.

Plaintiffs further allege pollution "associated with the opioid crisis" that "takes place in public streets, parks, and parking lots, where the Municipalities bear the cost of cleaning up human waste, used needles, and trash discarded by people who have entered the Municipalities to obtain drugs." Id. ¶ 118. While Sigman indicated that environmental pollution, such as a chemical or oil spill, may warrant recovery insofar as they constitute "physical harm to both person and property," see 2016 WL 2622007, at *2, plaintiffs' injuries relate to the cost of cleaning litter and clearing houses owned by non-parties. Nor do plaintiffs raise nuisance or other types of intangible claims for which the economic loss doctrine would not apply. See Aikens, 541 S.E.2d at 591. Plaintiffs simply seek to recoup the costs of government services provided in response to the

opioid crisis, which falls within the scope of "economic loss."

See Monroe County, 2020 WL 2090355, at *19.

Regarding plaintiffs' second argument that they do not allege losses stemming from an interruption in commerce, the complaint explicitly alleges disruptions to commerce. See Compl. ¶ 31 ("significant public safety costs and disruptions to quality of life and commerce") (emphasis added). Moreover, City of Chicago rejected similar arguments, where even though the city claims did not involve "disappointed commercial expectations," the same concerns "regarding speculativeness and potential magnitude of damages" were present in the city's claims against the gun manufacturers. 821 N.E.2d at 1139, 1143. Aikens expressed similar concerns inasmuch as it adopted the economic loss rule, in part, to "provid[e] a barrier against limitless liability" and to prevent these types of "chain-of-reaction" claims. 541 S.E.2d at 590-92.

Finally, plaintiffs argue that they do not allege "injury to the property of a third person." Aikens, 541 S.E.2d at 580. This argument has no merit. Plaintiffs are third parties several steps removed from defendants, seeking to recover based on defendants' alleged negligence in issuing the PM Standards to HCOs.

Therefore, in the absence of physical harm to their person or property, plaintiffs must allege a "special relationship" or "privity of contract" as required under Aikens. See White v. AAMG Const. Lending Ctr., 700 S.E.2d 791, 798 (W. Va. 2010) ("Whether a defendant has a special relationship with a plaintiff . . . is a determination that must be rendered by a court as a matter of law."). As Aikens explained:

The existence of a special relationship will be determined largely by the extent to which the particular plaintiff is affected differently from society in general. It may be evident from the defendant's knowledge or specific reason to know of the potential consequences of the wrongdoing, the persons likely to be injured, and the damages likely to be suffered. Such special relationship may be proven through evidence of foreseeability of the nature of the harm to be suffered by the particular plaintiff or an identifiable class and can arise from contractual privity or other close nexus.

541 S.E.2d at 589.

The court continued to list examples of these types of special relationships:

[A]uditors have been held liable to plaintiffs who bought stock in reliance upon a financial statement negligently prepared for a corporation; surveyors and termite inspectors liable to remote purchasers of property; engineers and architects liable to contractors who relied upon plans negligently prepared for property owners who later hired the contractors; attorneys and notaries public liable to beneficiaries of negligently prepare[d] wills; real estate brokers for failure to disclose defects; and telegraph companies liable to individuals who failed to secure a

contract due to the negligent transmission of a message.

Aikens, 541 S.E.2d at 590–91 (internal citations omitted); see also Eastern Steel Constructors, Inc. v. City of Salem, 549 S.E.2d 266, 275 (W. Va. 2001) (holding “that a design professional (e.g. an architect or engineer) owes a duty of care to a contractor, who has been employed by the same project owner as the design professional and who has relied upon the design professional’s work product in carrying out his or her obligations to the owner”).

By contrast, White v. AAMG Construction Lending Center held that the plaintiff borrower’s negligence claim that the defendant lender bank failed to properly inspect the borrower’s new house could not survive summary judgment because no special relationship existed between the parties. 700 S.E.2d 791, 799–800 (W. Va. 2010). It reached this conclusion after finding “no evidence that the Bank independently inspected the plaintiff’s new home to assess the quality or integrity of the construction, and no evidence that the Bank withheld any information about the quality or integrity of the home from the plaintiffs.” Id. at 800.

Plaintiffs argue that the complaint alleges a “special relationship” because it quotes TCJ’s mission to “continuously improve health care for the public, in collaboration with

other stakeholders," and alleges that TJC "views the government and the public as 'stakeholders.'" See Compl.

¶ 14. Plaintiffs also point to allegations that they are the "first responders" in the opioid crisis. Id. ¶¶ 31, 109. Plaintiffs contend that "White does not apply because Defendants not only withheld information, but also created misinformation" by promulgating the PM Standards. ECF No. 28 at 23.

Putting aside the complaint's general reference to TJC's "stakeholders," the relationship must not only be "special" but also "narrowly defined." Aikens, 541 S.E.2d at 590. For example, White found a special relationship lacking when the plaintiff "has directed us to no facts indicating how the plaintiff was affected differently from society in general, or how the Bank had a specific reason to know of any tort damages or consequences likely to be suffered by the plaintiff." 700 S.E.2d at 800. The complaint's allegation that defendants have a relationship with "the government and the public" is not "narrowly defined" nor does it indicate that plaintiffs were "affected differently from society in general." Aikens, 541 S.E.2d at 589. Plaintiffs here do not allege that they themselves ever relied upon the PM Standards.

The complaint acknowledges that these harms were felt universally, noting that the opioid crisis "impair[ed] the

quality of life for everyone in each Municipality." Compl.

¶ 31. That would include one who became addicted to opioids, the members of his or her immediate family who dealt with the addict's condition, the employer who lost the steady, competent services of the user or the affected family members, the owner whose property was invaded as the user turns to crime to support a drug habit. Recognizing a special relationship here opens defendants up to "limitless liability" to the whole public, which the economic loss doctrine expressly seeks to prevent. Aikens, 541 S.E.2d at 590. There is no "special relationship" or "privity of contract" here to preclude the application of the economic loss rule.

b. Foreseeability

Irrespective of the economic loss rule, plaintiffs fail to show defendants owed plaintiffs a duty. The existence of a duty intertwines with the foreseeability of the injury. The Supreme Court of Appeals has explained the importance of foreseeability as follows:

The ultimate test of the existence of a duty to use care is found in the foreseeability that harm may result if it is not exercised. The test is, would the ordinary man in the defendant's position, knowing what he knew or should have known, anticipate that harm of the general nature of that suffered was likely to result?

Syl. Pt. 3, Sewell v. Gregory, 371 S.E.2d 82, 83 (W. Va. 1988). “[F]oreseeability of risk is a primary consideration in determining the scope of a duty an actor owes to another.” Aikens, 541 S.E. 2d at 581 (citing Robertson v. LeMaster, 301 S.E.2d 563, 568 (W. Va. 1983)). “In a similar vein,” the Supreme Court of Appeals has held that “[d]ue care is a relative term and depends on time, place, and other circumstances. It should be in proportion to the danger apparent and within reasonable anticipation.” Robertson, 301 S.E.2d at 568 (alteration in original) (quoting Syl. Pt. 2, Johnson v. United Fuel Gas Co., 166 S.E. 118 (W. Va. 1932)).

The complaint alleges that “[d]efendants owed a duty of care to the Municipalities, including but not limited to taking steps to promulgate reasonable health care standards that would not lead directly to the misuse, abuse, and over-prescription of opioids.” Compl. ¶ 144. Defendants allegedly breached this duty “by fostering dangerous pain control practices, the endpoint of which is often the inappropriate provision of opioids with disastrous adverse consequences for individuals, families and communities.” Id. (internal quotation marks omitted). Defendants argue that nothing in the PM Standards or defendants’ conduct in promoting and publishing these materials establish that the risk to plaintiffs was

foreseeable. They maintain that plaintiffs have not pled facts to establish a link between defendants' conduct and a specific harm, including any allegations that the Municipalities read the PM Standards or any other reason that defendants could have reasonably expected them to rely upon these materials. See ECF No. 20 at 8-10.

In Summit County, the district court found that the opioid manufacturers owed a common law duty of care to the plaintiff municipalities when it was foreseeable that failing to implement adequate controls in the marketing, distribution, and prescription of opioids would force municipalities to bear the costs associated with the oversupply and over-prescription of the drugs. No. 1:17-MD-2804, 2018 WL 6628898, at *18-19 (N.D. Ohio Dec. 19, 2018). The court provided the following rationale:

Despite Manufacturer Defendants' marketing campaign to the contrary it is well known that opioids are highly addictive. When there is a flood of highly addictive drugs into a community it is foreseeable—to the point of being a foregone conclusion—that there will be a secondary, "black" market created for those drugs. It is also foreseeable that local governments will be responsible for combatting the creation of that market and mitigating its effects.

Id. at *19.

Here, plaintiffs assert that the "scientific underpinnings" for TJC's assertions were "highly questionable"

inasmuch as defendants "made no effort" until recently to "investigate the quality or accuracy of the research reported in the [1980 New England Journal of Medicine] Letter."

Compl. ¶¶ 48-50. Plaintiffs point to the April 2016 letter from Physicians for Responsible Opioid Prescribing asking TJC to reexamine the PM Standards and warning that they continue to "foster dangerous pain control practices." Id. ¶¶ 2, 82. Plaintiffs also quote an August 26, 2016 letter from United States Surgeon General Vivek Murthy, who explained:

Nearly two decades ago, we were encouraged to be more aggressive about treating pain, often without enough training and support to do so safely. This coincided with heavy marketing of opioids to doctors. Many of us were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain.

Id. ¶ 85.b.

TJC allegedly "zealously enforces these dangerous Standards through its certification program and has persisted in this course of action" even though it has reason to know that Purdue minimized the risks and overstated the efficacy of its opioid OxyContin. Id. ¶ 2. In 2003, for instance, the Food and Drug Administration ("FDA") requested that Purdue cease disseminating advertisements that failed to include the limitations of using OxyContin and the potentially fatal risks of its abuse. Compl. ¶¶ 57-59. The complaint further explains

that Purdue pled guilty to felony criminal charges in 2007, through which it admitted that its sales representatives told health care providers that OxyContin had less abuse and addiction potential than other painkillers. Purdue also admitted that its "supervisors and employees, with the intent to defraud or mislead, marketed or promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications." Id. ¶¶ 69-70.

Still, the foreseeability of the risk must be "proportion[al] to the danger apparent and within reasonable anticipation." Robertson, 301 S.E.2d at 568. Unlike the manufacturer and distributor defendants in Summit County, defendants here had no control or responsibility over the manufacturing or distributing of opioids. Although the 2001 NPC Monograph and 2001 TJC Monograph refer to opioids, the PM Standards themselves did not even mention opioids or mandate opioid prescriptions.

Moreover, defendants argue persuasively that independent standards organizations like themselves do not generally owe a duty to the intended recipients of those standards, let alone third parties. ECF No. 20 at 16-18. Defendants rely on Bailey v. Edward Hines Lumber Co., 719 N.E.2d

178 (Ill. App. Ct. 1999) in addition to several trade association cases discussed therein. ECF No. 20 at 16-17 (citing Evenson v. Osmose Wood Preserving, Inc., 760 F. Supp. 1345, 1349 (S.D. Ind. 1990) (emphasis added) (declining to impose duty on trade association which "did not manufacture, sell[,] distribute, design, test, conduct safety research on, or set standards for" using chemicals in pesticide); Friedman v. F.E. Myers Co., 706 F. Supp. 376, 383 (E.D. Pa. 1989) (trade association of water pump manufacturers owed no duty to user of contaminated water); Gunsalus v. Celotex Corp., 674 F. Supp. 1149, 1157 (E.D. Pa. 1987) (tobacco trade association owed no duty to smoker); Klein v. Council of Chem. Ass'ns, 587 F. Supp. 213, 225 (E.D. Pa. 1984) (trade associations not liable to printing industry worker); Meyers v. Donnatacci, 531 A.2d 398, 403 (N.J. Super. Ct. 1987) (trade association which promulgated voluntary, suggested standards for swimming pools owed no duty to consumer injured by swimming pool)).

In Bailey, the court concluded that the trade association did not owe a duty to carpenters even though they were the eventual intended users of the trade association's 'tentative recommendations' for bracing roof systems. 719 N.E.2d at 183. As plaintiffs note, Bailey found that it was "the lack of oversight and control over the use of the

'tentative recommendations' that speaks persuasively against the existence of a duty." Id. It distinguished its holding from cases where "the trade associations exercised a degree of control over their members well above that which [the defendant trade association] may have enjoyed in disseminating its 'tentative recommendations' to be used 'only as a guide.'" Id. at 182-83 ("The courts in these cases declined to impose a duty on the trade associations either because they did not manufacture the injury-causing products or because they did not exercise control over the manufacturers of those products.").

Plaintiffs point to Snyder v. American Association of Blood Banks, where the New Jersey Supreme Court held that the American Association of Blood Banks ("AABB") owed a duty of care to blood transfusion recipients because "state and federal government, as well as the blood-banking industry, generally accept AABB standards as authoritative" and the AABB "conditions accreditation on compliance with [its] standards." 676 A.2d 1036, 1040 (N.J. 1996). Indeed, the New Jersey Department of Health required blood banks to meet certain AABB standards. Id. at 1051. Insofar as plaintiffs assert that defendants dominate the accreditation industry just as the AABB "dominated the establishment of standards for the blood-banking industry," id. at 1048, plaintiffs concede that the PM Standards "never overtly

required opioid treatments." Compl. ¶ 56. Plaintiffs allege that TJC "zealously enforces" the PM Standards, though they do not specify whether strict compliance with the PM Standards is a necessary precondition of accreditation. Compl. ¶ 2. The complaint, of course, lacks any allegations that the municipalities were the intended recipients of the PM Standards, or that defendants specifically invited municipalities to rely on the PM Standards.

On the other hand, the AABB owed a duty to the blood transfusion recipients and their families in Snyder because the court found some close connection between the parties. 676 A.2d at 1048 (although "the AABB had no immediate connection with either the donor or with Snyder . . . the AABB invited blood banks, hospitals, and patients to rely on the AABB's recommended procedures"); see also Weigand v. University Hospital of New York University Medical Center, 659 N.Y.S.2d 395, 399 (N.Y. Sup. Ct. 1997) ("[T]he relationship between a standard-setting industry association and the ultimate recipient of a transfusion, although not a direct relationship, is one in which the conduct of the industry association may have a direct effect on the recipient."). The language of the PM Standards indicates that they were designed to influence HCOs, their medical professionals, and patients. There are no allegations to show

that plaintiffs themselves were invited to rely upon the PM Standards.

Moreover, Snyder stands apart. "[C]ourts have repeatedly held that trade associations, themselves, have no duty to users of products in that trade," and have "heavily criticized" the "cases where claims against trade associations based on an assumed duty were allowed." See In re Welding Fume Prod. Liab. Litig., 526 F. Supp. 2d 775, 799, 800 n.114 (N.D. Ohio 2007) (emphasis in original) (listing cases). The court here concludes that plaintiffs have not alleged facts to plausibly show that defendants could reasonably foresee the harms described in the complaint.

c. Additional Considerations

"Beyond the question of foreseeability, the existence of duty also involves policy considerations underlying the core issue of the scope of the legal system's protection."

Robertson, 301 S.E.2d at 568. These policy factors "include the likelihood of injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant." Id.

Respecting the likelihood of injury, plaintiffs allege that TJC "certifications are viewed by health care organizations

as critical to their continued operation" inasmuch as TJC accredits "99% of health care organizations in the United States." Compl. ¶¶ 16, 88. Therefore, plaintiffs posit, it was likely that the PM Standards would "result in widespread addiction and concomitant societal disruption." ECF No. 28 at 19. Although some of the earlier monographs, educational materials, and programs directly referred to opioids, see Compl. ¶¶ 46-47, 51, 62-63, the actual PM Standards did not reference opioids until the Clarification to Standard PC.01.02.07 issued in 2014, which provided "not exhaustive" examples of nonpharmacologic and pharmacologic strategies, including both nonopioids and opioids as potential strategies. Compl. ¶¶ 56, 79. Plaintiffs acknowledge that the PM Standards were not mandatory, and that HCOs may seek accreditation through another accreditation organization or rely on periodic inspections from the West Virginia Department of Health. W. Va. Code § 16-5B-5a.

Plaintiffs next argue that imposing this duty upon defendants to prevent the harms alleged does not add an unreasonable burden on defendants because governments and the health care industry already grant TJC a "sacred trust" by recognizing its role in the certification and accreditation of HCOs. Id. ¶ 19 (citing W. Va. Code § 16-5B-5a). To be

sure, defendants already seek "to develop standards related to safe and judicious prescribing of opioids." See Compl. ¶ 87.

Still, the consequences of imposing this duty on defendants would expose them to a liability to the public at large with no manageable limits. Aikens noted that "[e]ach segment of society will suffer injustice, whether situated as plaintiff or defendant, if there are no finite boundaries to liability." 541 S.E.2d at 592. The "[c]ourt's obligation is to draw a line beyond which the law will not extend its protection in tort, and to declare, as a matter of law, that no duty exists beyond that court-created line." Id. Several intermediaries stand in between plaintiffs and defendants, including the HCOs responsible for issuing their own pain management protocols, the medical practitioners responsible for issuing opioid treatments, as well the pharmaceutical manufacturers, distributors, and retailers who bring the opioids to market in the first place. These intermediaries tie into defendants' arguments that the learned intermediary doctrine precludes imposing a duty as well.

The learned intermediary doctrine "stands for the proposition that a drug manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." State ex rel. Johnson & Johnson Corp. v. Karl, 647

S.E.2d 899, 902-03 (W. Va. 2007) superseded by statute, W. Va. Code. § 55-7-30 (2016) (internal quotation marks omitted). Up until recently, West Virginia "had previously declined to adopt the doctrine." J.C. by & through Michelle C. v. Pfizer, Inc., 814 S.E.2d 234, 238 n.9 (W. Va. 2018) (citing Karl, 647 S.E.2d 899).

The parties point the court to Tyree v. Boston Scientific Corp., which concluded "that the learned intermediary doctrine would apply in West Virginia [to preclude patients' claim that manufacturer had duty to warn patients directly] where a device manufacturer has not participated in [direct-to-consumer] advertising." 56 F. Supp. 3d 826, 833 (S.D.W. Va. 2014) (citing Karl, 647 S.E.2d at 907). In 2016, the West Virginia legislature clarified its policy preference "to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices." W. Va. Code. § 55-7-30. The statute provides that manufacturers or sellers of prescription drugs or medical devices will not be liable for failure to warn unless:

(1) The manufacturer or seller of a prescription drug or medical device acted unreasonably in failing to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce

the risks of harm in accordance with the instructions or warnings; and
(2) Failure to provide reasonable instructions or warnings was a proximate cause of harm.

Id.

The statute incorporates the West Virginia Supreme Court's "long-standing restriction of products liability to the manufacturer and seller of the allegedly injury-causing product." McNair v. Johnson & Johnson, 818 S.E.2d 852, 866-67 (2018) (applying § 55-7-30 and "declin[ing] to distort [West Virginia's] products liability law to hold a brand manufacturer liable for injuries allegedly caused by a generic drug that the brand manufacturer neither manufactured nor sold").

The learned intermediary doctrine provides a further barrier to imposing a duty here where the independent medical practitioners assumed ultimate responsibility for advising patients about opioid risks and, compared to the opioid manufacturers themselves, defendants are at least one step further removed from the individual patients. West Virginia leaves it to drug manufacturers and sellers "to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." W. Va. Code § 55-7-30.

Plaintiffs argue that defendants deprived patients of key information and overrode the learned intermediaries' independent judgment by instructing that "[p]ain is assessed in all patients," or, in the words of the April 2016 letter from Physicians for Responsible Opioid Prescribing, "[m]andating routine pain assessments for all patients." ECF No. 28 at 20; Compl. ¶¶ 37, 82.a-b. The complaint alleges that defendants "framed opioids as a patients' rights issue" and suggested that doctors "who did not provide opioids were failing as physicians and perhaps risking liability for not making patients pain-free." Id. ¶ 56. Defendants hosted educational programs to correct "[c]linicians' misconceptions about pain treatments' including 'an exaggerated fear of addiction resulting from use of opioids.'" Id. ¶ 51. The 2003 TJC Monograph notes, "Scrutiny of physician practice" in recent court cases "increasingly" includes the investigation of "cases of underprescribing." Id. ¶ 62.b. The complaint also alleges that defendants produced materials "designed for distribution to patients" in an effort to downplay addiction as "unlikely." Id. ¶ 78.

Although the West Virginia Supreme Court declined to adopt the doctrine prior to 2016, it laid out the "primary justifications" advanced in favor of the doctrine as follows:

(1) the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs; (2) patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs; (3) the fact that it is physicians who exercise their professional judgment in selecting appropriate drugs; (4) the belief that physicians are in the best position to provide appropriate warnings to their patients; and (5) the concern that direct warnings to ultimate users would interfere with doctor/patient relationships.

Karl, 647 S.E.2d at 905.

These same justifications point against the imposition of a duty here. The complaint alleges that the recommendations in the PM Standards were unwarranted because "[h]ealth care professionals are capable of using their clinical judgment to determine when to assess patients for pain." Compl. ¶ 82.b. Yet, this acknowledges the corollary principle that physicians exercise their independent clinical judgment in patient evaluations, including when deciding whether to prescribe opioid treatments.

Plaintiffs here are not patients who consumed any opioids. The Report and Recommendation in Summit County rejected arguments from the defendant retail pharmacies that they did not owe a duty of care as a result of the learned intermediary doctrine when defendants allegedly engaged in a "systematic campaign, based on allegedly false statements, that specifically targeted physicians" and aimed "to abolish concern

regarding opioid addiction/abuse." 2018 WL 4895856, at *14, *37 report and recommendation adopted in relevant part, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018) (emphasis in original). Still, the court finds this case distinguishable inasmuch as it does not involve the manufacturers, distributors, prescribers or sellers themselves but an independent accreditation organization without any direct connection to plaintiffs.

The court accepts plaintiffs' allegations of the scope and devastation wreaked by the opioid crisis in these communities. Compl. ¶ 7. As the complaint notes, "Addiction rips apart families, causes overwhelming grief, demolishes productivity, imposes financial ruin, and imparts death and destruction not only on those who suffer directly from the disease, but also upon their families, friends, employers, and communities." Id. ¶ 6. The enormous scale of the opioid crisis has reached almost every corner of society, but the court must draw a line somewhere. It cannot extend a duty to the full constellation of individuals and communities who have suffered in the wake of the opioid crisis without running afoul of Aikens.

Plaintiffs have not shown that defendants owed a duty of care to municipalities when it promulgated and promoted the PM Standards. Because plaintiffs fail to establish the element

of duty necessary to their negligence claim, the claim must be dismissed.

d. Gross Negligence and Reckless and Willful Conduct

Plaintiffs do not offer any specific arguments to support separate claims of gross negligence and reckless and willful conduct under Count I. Ordinary negligence and gross negligence generally involve the same basic elements, differing only in the degree of actionable inattention on the defendant's part. See Wood v. Shrewsbury, 186 S.E. 294, 296-97 (W. Va. 1936) (Where the plaintiff seeks to establish gross negligence, he must present "affirmative proof tending to magnify the negligence.").¹⁵ West Virginia "recognizes a distinction between negligence, including gross negligence, and wil[l]ful, wanton, and reckless misconduct." See Mandolidis v. Elkins Indus., Inc., 246 S.E.2d 907, 913 (W. Va. 1978) (superseded by statute on other grounds); Groves v. Groves, 158 S.E.2d 710, 713 (W. Va. 1968); Korzun v. Shahan, 151 S.E.2d 287, 293 (W. Va. 1966).

¹⁵ "While the West Virginia Supreme Court of Appeals has never provided its own definition of gross negligence, it has interpreted Virginia law to define gross negligence as the 'degree of negligence which shows an utter disregard of prudence amounting to complete neglect of the safety of another.'" Rutecki v. CSX Hotels, Inc., 290 F. App'x 537, 542-43 (4th Cir. 2008) (quoting Dodrill v. Young, 102 S.E.2d 724, 730 (W. Va. 1958)).

To establish willful conduct, a plaintiff must show that a defendant "was conscious of his conduct, and conscious, from his knowledge of existing conditions, that injury would likely or probably result from his conduct, and that with reckless indifference to consequences [it] consciously and intentionally did some wrongful act or omitted some known duty which produced the injurious result." Stone v. Rudolph, 32 S.E.2d 742, 749-50 (1944) (quoting Thomas v. Snow, 174 S.E. 837, 839 (Va. 1934)); accord Groves, 158 S.E.2d at 713.

The lack of foreseeability or duty of care precludes any showing that defendants were grossly negligent or conscious that the injury to plaintiffs was the likely or probable result of their conduct. Accordingly, Count I must be dismissed as to the claims of gross negligence and reckless and willful conduct as well.

D. Counts I and II: Proximate Cause

Defendants next argue that plaintiffs' complaint does not satisfy federal pleading standards on all counts as it "fails to allege facts sufficient to establish that Defendants' conduct caused the injuries alleged." ECF No. 20 at 22. They assert that the connection between defendants' conduct and the alleged injuries is too remote to be the proximate cause and that the learned intermediary doctrine as well as the

intervening illegal acts of third parties broke the chain of causation. Id. at 13-16, 23-26; ECF No. 32 at 7-13.

With respect to Count II, the elements of a claim for unjust enrichment in West Virginia are: "(1) a benefit conferred upon the [defendant], (2) an appreciation or knowledge by the defendant of such benefit, and (3) the acceptance or retention by the defendant of the benefit under such circumstances as to make it inequitable for the defendant to retain the benefit without payment of its value." Employer Teamsters-Local Nos. 175/505 Health & Welfare Tr. Fund v. Bristol Myers Squibb Co., 969 F. Supp. 2d 463, 471 (S.D.W. Va. 2013) (citations and internal quotation marks omitted) (alteration in original). Plaintiffs claim that Purdue and other pharmaceutical companies "co-opted" defendants to issue and promote PM Standards that failed to recognize the dangerous and addictive nature of opioids. Although the complaint acknowledges that TJC's \$150 million in annual revenue comes "largely from its certification programs," plaintiffs claim that any funding defendants received from pharmaceutical companies,¹⁶ such as Purdue's funding for TJC's pain management educational programs or Janssen Pharmaceuticals' funding of the 2012 JCR Monograph, constituted

¹⁶ The complaint does not specify how much funding defendants received from pharmaceutical companies.

"blood money." Compl. ¶¶ 54, 75, 149-50. Plaintiffs seek "these funds to remediate Defendants' failings." Id. ¶ 152.

However, plaintiffs must plead proximate causation to support their unjust enrichment claim. See Employer Teamsters, 969 F. Supp. 2d at 472-76 (dismissing unjust enrichment claim for lack of "sufficient allegations from which to properly infer that proximate causation is satisfied"); see also Bertovich, 2006 WL 2382273, at *4 (dismissing entire complaint, which included unjust enrichment claim, because plaintiffs "do not allege any facts that would connect any of the Defendants' conduct to [plaintiffs'] injury"). With respect to Count I as well, "negligence must be the proximate cause of the injury complained of and must be such as might have been reasonably expected to produce an injury." Syl. Pt. 6, Aikens. While West Virginia generally treats proximate cause as a factual question for the jury, the court may rule on it as a matter of law when there is no conflicting evidence and reasonable minds could not differ on the facts. Id. at 580.

West Virginia defines proximate cause "as that cause which, in actual sequence, unbroken by any independent cause, produced the event, without which such event would not have occurred." Webb v. Sessler, 63 S.E.2d 65, 68 (W. Va. 1950). However, "[w]here there is a sole, effective intervening cause,

there can be no other causes proximately resulting in the alleged injury." Id. at 69. In order for an intervening cause to break the chain of causation, it "must be a negligent act, or omission, which constitutes a new effective cause and operates independently of any other act, making it and it only, the proximate cause of the injury." Syl. Pt. 3, Wehner v. Weinstein, 444 S.E.2d 27 (W. Va. 1994).

Although the West Virginia Supreme Court has noted in dicta that "[g]enerally, a willful, malicious, or criminal act breaks the chain of causation," see Yourtee v. Hubbard, 474 S.E.2d 613, 620 (W. Va. 1996), it does not treat criminal acts as per se intervening causes that negate proximate cause. Marcus v. Staubs, 736 S.E.2d 360, 372 (W. Va. 2012). Rather, a "tortfeasor whose negligence is a substantial factor in bringing about injuries is not relieved from liability by the intervening acts of third persons if those acts were reasonably foreseeable by the original tortfeasor at the time of his negligent conduct." Syl. Pt. 13, id. The proper inquiry is whether it was reasonably foreseeable by defendants that the intervening acts - criminal or otherwise - would occur when defendants promulgated the PM Standards.

Defendants primarily argue that the alleged harms here are too remote to be actionable, relying on City of

Philadelphia, Ashley County, and other cases that found proximate cause lacking where municipalities sued companies that manufacture or market products such as guns, cold medicine, tobacco, and alcohol. ECF No. 20 at 23-24; ECF No. 32 at 7-10. City of Philadelphia relied on the proximate cause principles set forth in Holmes v. Securities Investor Protection Corporation, where the United States Supreme Court held in the context of RICO claims that "a plaintiff who complain[s] of harm flowing merely from the misfortunes visited upon a third person by the defendant's acts [is] generally said to stand at too remote a distance to recover." City of Philadelphia, 277 F.3d at 423 (alterations in original) (quoting Holmes, 503 U.S. 258, 268-69 (1992)). Holmes recognized that proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged." 503 U.S. at 268.

Holmes enunciated this rule based on its holding that to state a claim for a RICO violation pursuant to RICO Section 1964(c), plaintiffs must "show[] that the defendant's violation not only was a 'but for' cause of his injury, but was the proximate cause as well." 503 U.S. at 268; Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 461 (2006) ("When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the

plaintiff's injuries."). Unlike the proximate cause analysis for negligence claims under West Virginia law, the injury and causation components of RICO claims, i.e., the "direct relation" test, are viewed as standing requirements that must be established at the motion to dismiss stage. See Gallant v. Deutsche Bank Nat. Tr. Co., 766 F. Supp. 2d 714, 722 (W.D. Va. 2011) (citing Field v. GMAC LLC, 660 F. Supp. 2d 679, 686 (E.D. Va. 2008)); Syl. Pt. 5, Hatten, 135 S.E.2d at 238.

Nevertheless, courts have applied the principles of remoteness to state law tort claims insofar as proximate cause requires "carefully drawing a line so as to distinguish the direct consequences in a close causal chain from more attenuated effects influenced by too many intervening causes." See Employer Teamsters, 969 F. Supp. 2d at 472-73 (applying Holmes "direct relation" proximate cause standard when dismissing breach of implied warranty of merchantability and unjust enrichment claims); see also City of Philadelphia, 126 F. Supp. 2d at 903.¹⁷ This comports with the principle that "the

¹⁷ Although some courts have applied the concept of remoteness to questions of standing, defendants raised this theory with respect to pleading proximate causation. See White v. Smith & Wesson Corp., 97 F. Supp. 2d 816, 823 (N.D. Ohio 2000) (clarifying that "remoteness" is not an independent doctrine but "either relates to, and is merely an element of, whether a plaintiff properly has standing to bring a claim or whether a plaintiff has shown the existence of proximate causation as an element of a specific claim").

negligence which renders a defendant liable for damages must be a proximate, not a remote, cause of injury." Metro v. Smith, 124 S.E.2d 460, 464 (W. Va. 1962).

Applying the Holmes framework to the plaintiffs' negligence-based claims, City of Philadelphia affirmed that the defendant gun manufacturers did not intend to harm the plaintiffs (which included the city itself and five civic organizations referred to as the "organizational plaintiffs"), the organizational plaintiffs' injuries were derivative of those of gun victims, and the damages were too speculative inasmuch as "it would be difficult to calculate how many incidents could have been avoided had the gun manufacturers adopted different policies." 277 F.3d at 425.

Defendants here primarily point to the City of Philadelphia holding that the following "long and tortuous" causal chain failed to demonstrate proximate cause:

First, the defendant manufacturers sell guns to licensees; second, the licensees sell the guns to dealers; third, the dealer sells it to a lawful purchaser acting as a straw buyer; fourth, the straw buyer transfers the weapon to a criminal or a youth; fifth, the transferee uses the gun to commit a crime, or the youth injures himself or a companion; and finally, demand on the City's or the organizational plaintiffs' resources is increased.

277 F.3d at 423-24; see also ECF No. 32 at 8 (citing 126 F. Supp. 2d at 903-906). The Third Circuit found that none of the

illicit buyers dealt with the manufacturers directly and the distribution scheme linking manufacturers to licensed distributors and dealers was "not only lawful, but also is prescribed by statute with respect to the manufacturers' conduct." 277 F.3d at 424. The Third Circuit concluded that "[t]hose immediately and directly injured by gun violence—such as gunshot wound victims—are more appropriate plaintiffs than the City or the organizational plaintiffs whose injuries are more indirect." See City of Philadelphia, 277 F.3d at 425.

Ashley County relied on Arkansas law that "an original action can be too remote or indirect to be considered the legal cause of a subsequent injury," see 552 F.3d at 667 (citing State Farm Mut. Auto. Ins. Co. v. Pharr, 808 S.W.2d 769, 772 (Ark. 1991)), and City of Philadelphia's reasoning in holding that the defendant manufacturers and distributors of over-the-counter cold medicine containing pseudoephedrine did not proximately cause the counties' damages, which included expenditures on governmental services responding to the methamphetamine epidemic. Id. at 669. The Arkansas counties in Ashley County alleged that the defendants failed to take steps to restrict access to products containing pseudoephedrine when they allegedly knew that people were buying the medicine to illegally make methamphetamine. Id. However, there were

several intervening causes, including "the conduct of the independent retailers in selling the products; the illegal conduct of methamphetamine cooks purchasing the cold medicine . . . ; the illegal conduct of cooking the items into methamphetamine; and the illegal conduct of distributing the methamphetamine to others in Arkansas." Id. at 667-68. The court concluded that even if the defendants knew that the medicine was being purchased to make methamphetamine, the illegal conduct of methamphetamine cooks and others down the causal chain were "sufficient to stand as the cause of the injury." Id. at 670 (quoting City of Caddo Valley v. George, 9 S.W.3d 481, 487 (Ark. 2000)). It also found that — like the sale of guns to independent, licensed distributors in City of Philadelphia — the sale of medicine containing pseudoephedrine is highly regulated and sold to independent retailers before reaching methamphetamine "cooks." Ashley County, 552 F.3d at 669.

Both City of Philadelphia and Ashley County found it significant that these products (guns and cold medicine, respectively), were highly regulated and sold via independent, licensed distributors before they were later misused. City of Philadelphia, 277 F.3d at 424; Ashley County, 552 F.3d at 669. Ashley County also worried about the policy implications of

"open[ing] Pandora's box to the avalanche of actions that would follow" if the court held drug manufacturers liable for the societal ills caused by the methamphetamine crisis. 552 F.3d at 671 ("We could easily predict that the next lawsuit would be against farmers' cooperatives for not telling their farmer customers to sufficiently safeguard their anhydrous ammonia¹⁸ . . . tanks from theft by methamphetamine cooks.").

In Bertovich, the Northern District of West Virginia dismissed the class action complaint of parents against alcohol companies and trade association because the complaint failed to sufficiently allege causation for the negligence, unjust enrichment, and other state law claims. 2006 WL 2382273, at *9. The court also found that the intervening illegal acts broke the chain of causation because "[i]n order for an underage person to consume alcohol, there must be at least one illegal act, whether it is a retailer selling alcohol to an underage consumer or a person of age purchasing alcohol for someone underage." Id. at *11. The court also found that it was "unforeseeable that the marketing practices of the Defendants would lead to the illegal purchase or sale of alcoholic beverages to minors" because inspiring minors to drink does not inherently amount to

¹⁸ Anhydrous ammonia is another ingredient in illicit methamphetamine manufacture.

an injury. Id. Inasmuch as defendants sold their products to third party wholesalers approved by the state, who in turn sell the products to retailers, "at least two levels of third parties must intervene by violating the law" for plaintiffs to suffer any injury. Id.

These results stand in contrast to the MDL against retail pharmacies and opioid manufacturers and distributors in the Northern District of Ohio. Summit County denied a motion to dismiss the claims filed by municipal plaintiffs even where the defendant manufacturers argued that their conduct ("deceptive claims in promoting its opioids") and plaintiffs' injury (expending resources on emergency services and lost tax revenue) was separated by a long chain of events. 2018 WL 6628898, at *5. The court concluded that plaintiffs pled sufficient facts to show a more direct chain:

(i) RICO Marketing Defendants made deceptive claims in promoting their opioids in order to sell more opioids than the legitimate medical market could support (the conduct); (ii) the excess opioids marketed by the RICO Marketing Defendants and distributed by the RICO Supply Chain Defendants were then diverted into an illicit, black market; (iii) Plaintiffs were forced to expend resources beyond what they had budgeted to attempt to stop the flow of the excess opioids into local communities and to bear the costs associated with cleaning them up.

Id.

Plaintiffs also cite to City of Everett v. Purdue Pharma L.P., which found the following causal chain was a "direct sequence" sufficient to plead proximate cause:

(1) Purdue's affirmative action to continue to supply OxyContin through legal channels with knowledge that it was being diverted to a criminal drug ring, (2) the criminal conduct of the drug ring transferring and selling OxyContin, (3) the misuse and abuse of individual users located in Everett, (4) injuries to Everett bringing this action on behalf of the public.

No. C17-209RSM, 2017 WL 4236062, at *6 (W.D. Wash. Sept. 25, 2017); ECF No. 28 at 27. The plaintiff city alleged that Purdue "supplied OxyContin to obviously suspicious physicians and pharmacies;" "enabled the illegal diversion;" "aid[ed] criminal activity;" and "disseminated massive quantities of OxyContin . . . into the black market." Id. at *4 (emphasis and alterations in original).

A liberal reading of plaintiffs' claims show the following chain of events and intervening actors that link plaintiffs' injuries to the PM Standards: (i) After defendants promoted incorrect claims about the safety of opioids in promulgating the PM Standards and providing consulting services and accreditation to HCOs, (ii) HCOs adopted pain management protocols to ensure compliance with the PM Standards, (iii) licensed independent practitioners prescribed opioid medication based on these protocols and their own judgment,

(iv) which led to a flood of opioid medication as well as a black market for addicts, and (v) this crisis forced plaintiffs to expend far greater resources and expenditures to combat addiction, respond to crime, and to support the numerous other costs alleged in the complaint.

The court finds that plaintiffs have failed to plead that the pain management strategies promoted by defendants proximately caused the widespread societal ills and costs suffered by plaintiffs given the numerous intervening events and parties standing between them. Unlike Summit County and City of Everett, defendants had no role in manufacturing, distributing, or marketing opioids. The independent medical judgment of the prescribing physicians further breaks the chain of causation because, compared to the opioid manufacturers, defendants are one substantial step further removed from the individual patients and from the Municipalities. Cf. Employer Teamsters, 969 F. Supp. 2d at 475 (dismissing state law claims of implied warranty of merchantability and unjust enrichment brought by third party payors against drug manufacturer for lack of causation where "a vast array of intervening events, including the 'independent medical judgment' of doctors" stood between the alleged misleading marketing and the plaintiffs' prescription reimbursements).

Even if physicians followed the PM Standards and assessed pain in all patients, no injury would occur unless the physician proceeded to unnecessarily prescribe opioid treatments or if patients obtained the drugs through some other illegal means. Plaintiffs' claims rely on various criminal actions of third parties, such as "illegal drug trafficking," "criminal vagrancy," "stolen merchandise," and "property crimes," as triggering a need for increased governmental services and remediation. Compl. ¶¶ 113-114. As in Ashley County and City of Philadelphia, prescription opioids are highly regulated by federal agencies, such as the FDA, and require licensed independent professionals to distribute the medication through proper legal channels. Ashley County, 552 F.3d at 669; City of Philadelphia, 277 F.3d at 424. Nothing in the complaint indicates that defendants would reasonably foresee that recommending HCOs to assess pain in all patients and downplaying the risk of opioid treatments would result in these addiction-related crimes.

In sum, defendants' actions are too attenuated and influenced by too many intervening causes, including the criminal actions of third parties, to stand as the proximate cause of plaintiffs' injuries. Because plaintiffs have not alleged facts to plausibly plead a proximate cause, and

proximate cause is a necessary element of Counts I and II, these claims must be dismissed.

E. Count III: Declaratory and Injunctive Relief

Although Count III is titled, "Declaratory Judgment," it also indicates that plaintiffs seek injunctive relief. Count III concludes, "Plaintiffs seek the equitable relief of declaratory judgment, injunction, and remediation for the ongoing crisis of addiction Plaintiffs continue to endure." Compl. ¶ 159. Federal Rule of Civil Procedure 8(f) instructs that "[a]ll pleadings shall be so construed as to do substantial justice." Fed. R. Civ. P. 8(f); Cortez v. Prince George's Cty. Md., 31 F. App'x 123, 128 (4th Cir. 2002) ("Giving effect to this rule requires that a complaint be judged by its substance rather than according to its form or label and, if possible, should be construed to give effect to all its averments"). Whether the court construes Count III as a request for declaratory relief or injunctive relief or both, the question is whether plaintiffs have pled facts showing they are entitled to the relief sought. Iqbal, 556 U.S. 662.

That said, the court has no basis to grant declaratory relief inasmuch as plaintiffs fail to state a cause of action for their underlying claims. See Val-Com Acquisitions Tr. v. CitiMortgage, Inc., 421 F. App'x 398, 400-01 (5th Cir. 2011)

("In a declaratory judgment action, the parties litigate the underlying claim, and the declaratory judgment is merely a form of relief that the court may grant.").

To obtain a permanent injunction, a plaintiff must show: (1) an irreparable injury; (2) no other adequate remedy at law; (3) a balancing of hardships favors the plaintiff and remedy in equity is warranted; and (4) a showing that the injunction would not be against the public interest. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006). However, insofar as Count III seeks injunctive relief, an injunction is merely a remedy flowing from the underlying substantive claims rather than an independent cause of action itself. See Chruby v. Kowaleski, 534 F. App'x 156, 160 (3d Cir. 2013) (affirming dismissal of claims for declaratory and injunctive relief inasmuch as none of the substantive claims survived the motion to dismiss); Pinnacle Min. Co., LLC v. Bluestone Coal Corp., 624 F. Supp. 2d 530, 539 (S.D.W. Va. 2009); In re Shop-Vac Mktg. & Sales Practices Litig., 964 F. Supp. 2d 355, 365 (M.D. Pa. 2013); Jensen v. Quality Loan Serv. Corp., 702 F. Supp. 2d 1183, 1201 (E.D. Cal. 2010); Housecalls Home Health Care, Inc. v. U.S. Dep't of Health & Human Servs., 515 F. Supp. 2d 616, 627 n.6 (M.D.N.C. 2007) ("While the claim for injunctive relief is set out as a separate cause of action, it is really nothing more

than a form of possible relief that can be awarded once a party has prevailed on another cause of action.").

Inasmuch as the court's rulings leave plaintiffs without any other substantive causes of action, Count III must be dismissed as well.

IV. Amicus Curiae Briefs

Subsequent to their motions to dismiss and to strike class action allegations, defendants filed a motion for a scheduling order for submission of amicus curiae briefs. Therein, they contend that the American College of Surgeons, the American Dental Association, the American Medical Association, and "additional third parties" wish to be heard in connection with the motions to dismiss. ECF No. 35 at 2. Defendants contend that because their motions raise issues concerning public policy and the "potential impact on the quality of health care," the amicus briefs will help the court in ruling on the parties' motions in this case. ECF No. Id. at 2. The court's ruling herein renders the need for amicus briefs moot.


V. Conclusion

Accordingly, it is hereby ORDERED as follows:

1. JCR's motion to dismiss plaintiffs' complaint be, and it hereby is, granted.
2. TJC's motion to dismiss plaintiffs' complaint be, and it hereby is, granted.
3. Defendants' motion for scheduling order for submission of amicus curiae briefs be, and it hereby is, denied as moot.

The Clerk is directed to transmit copies of this memorandum opinion and order to all counsel of record and any unrepresented parties.

ENTER: July 20, 2020



John T. Copenhaver, Jr.
Senior United States District Judge